

REMARKS:

Claims 1-3 are the only claims now presented.

Claims 4 and 5 directed to the method of manufacturing the pharmaceutical composition of the present invention have been canceled, subject to applicant's right to file a possible continuation application covering these claims before abandonment or granting of any patent on the present application, and primarily to simplify the prosecution of the present case.

The applicants sincerely thank the Examiner for her careful reasoning and consideration of the previously filed amendment. They disagree with the Examiner's conclusions, however, and believe that in fact claims 1-3 are unobvious to the person having ordinary skill in this field in view of the cited prior art, namely, if the skilled artisan were to fully consider the combination of U.S. Patent 6,284,277 to Boulomie et al. and U.S. Patent 6,063,780 to Dexter et al., or independently if the skilled artisan were to combine the teachings of international application WO 94/12193 to Ibrahim et al. with the Boulomie and Dexter teachings.

In view of the Examiner's rejection of the arguments presented in the previous amendment which applicants had considered to be clear and persuasive concerning the non-obviousness of the claims invention, particularly as claimed in claims 1, 2 and 3, applicants new arguments will be presented by posing questions and analyzing the answers that should be reached based on a fair reading of the prior art, the present application and a consideration of the person having ordinary skill in the art of the present application. Such a person is likely to be a chemist with experience in pharmaceuticals, perhaps with a post-graduate degree and with several years experience in the field.

It is through that hypothetical persons eyes that the prior art references are to be considered under 35 U.S.C. 103.

Posing the first question:

Question 1: Could the ratio 1:4.5 of Dexter be helpful for the person skilled in the art working to develop a freeze-dried composition only comprising oxaliplatin and alcoholic sugar?

In the applicants' opinion, the answer must be no. This is because it will not be obvious that the ratio of 1:4.5, which is effective for lactose, which is not an alcoholic sugar, would also be effective for alcoholic sugars such as mannitol, having a chemical structure which is very different from that of lactose.

Question 2: Could the person skilled in the art working to develop a freeze-dried composition only comprising oxaliplatin and alcoholic sugar find helpful instruction from Boulomie's freeze-dried composition comprising oxaliplatin, the alcohol sugar mannitol and the amino acid alanine?

Here again, applicants believe that the fair and correct answer would be no since it is not at all obvious how the Boulomie composition would behave when not comprising the amino acid alanine.

Question 3: Could the person skilled in the art working to develop a freeze-dried composition only comprising oxaliplatin and alcoholic sugar be aided by the

combination of Boulomie and Dexter?

Here again, applicants believe the fair answer is no. Boulomie and Dexter teach freeze-dried compositions that are inconsistent with each other as they comprise different carriers (alcoholic sugar vs. non-alcoholic sugar). In other words, the person skilled in the art trying to develop the freeze-dried composition comprising an alcoholic sugar would look to prior art concerning the alcoholic sugars only. Thus, the skilled artisan would have no reason to utilize the prior art which does not comprise an alcoholic sugar.

It is believed that, in fact, the correct answers to the three foregoing questions are no and, that these answers evidence the unobviousness of the present invention as defined in claims 1, 2 and 3.

If the Examiner disagrees, it is requested that the reason why the answers to any of these questions should be yes, be placed in the record. If the Examiner, however, after considering these arguments comes to the same conclusion, then favorable action on claims 1-3 with respect to the combination of Boulomie and Dexter is respectfully requested.

Adding now a fourth question to address the citation of the Ibrahim reference:

Question 4: Does Ibrahim include helpful instructions leading to the weight ratio of oxaliplatin to the alcoholic sugar of from 1:3 to 1:7 as set forth in claim 1?

Applicants believe that the fair answer is no since the only values of the weight ratio

of oxaliplatin to the alcoholic sugar mentioned in Ibrahim are 1:15.4 (Example 1), 1:15.1 (Example 2) and 0.28:1 (Example 3). These values are far from the weight ratio called for in claim 1 and, certainly, not obvious variations of that ratio.

Applicants are therefore of the opinion, and the undersigned also believes, that claims 1-3 are not obvious from the combination of Ibrahim with Boulomie and Dexter.

To try and further emphasize this point, the Examiner is requested to consider the statement made in the Office Action of April 29, 2008 at page 8, lines 1 and 2, where it is stated that "The cited references disclose a freeze-dried composition having a mannitol (alcoholic sugar) with oxaliplatin in a ration [sic] of 1:4.5." This statement is, in fact, erroneous since the prior art does not disclose this at all. The Dexter ratio of 1:4.5 is in fact related to lactose, a non-alcoholic sugar and oxaliplatin.

Thus, the objection based on this ratio is not a fair basis for the rejection including the Dexter reference because of the answer to Question 1 above.

One further point concerns the Office Action of November 6, 2007, page 3, last full paragraph, where it is stated that Dexter teaches, among other things, a concentration ratio of 1:4.5 of the "alcoholic sugar lactose." Lactose, in fact, is not an alcoholic sugar but is a non-alcoholic sugar.

These two inaccuracies in the Office Actions are believed to highlight the unobviousness of the invention. The Examiner's incorrect identification of lactose as an alcoholic sugar it believed to have led to a feeling that, perhaps, the invention of claims 1-3 is obvious from a combination of Boulomie and Dexter or Boulomie, Dexter and Ibrahim, based perhaps not on the use of hindsight but on a misinterpretation of the Dexter teaching.

Accordingly, the Examiner is respectfully requested to reconsider the holding of obviousness and to now find claims 1, 2 and 3 unobvious and patentable over the combination of references for the reasons and, in particular, because of the questions posed above, and the answers which should reasonably follow.

Accordingly, the application and claims are believed to be in condition for allowance and favorable action is respectfully requested.

Respectfully submitted,

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